

(2) ISO/IEC GUIDE 65 General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for §170.420 and §170.423.

(3) [Reserved]

### Subpart E—Permanent Certification Program for HIT

SOURCE: 76 FR 1325, Dec. 7, 2011, unless otherwise noted.

#### § 170.500 Basis and scope.

This subpart implements section 3001(c)(5) of the Public Health Service Act and sets forth the rules and procedures related to the permanent certification program for health information technology (HIT) administered by the National Coordinator for Health Information Technology.

#### § 170.501 Applicability.

This subpart establishes the processes that applicants for ONC-ACB status must follow to be granted ONC-ACB status by the National Coordinator; the processes the National Coordinator will follow when assessing applicants and granting ONC-ACB status; the requirements that ONC-ACBs must follow to maintain ONC-ACB status; and the requirements of ONC-ACBs for certifying Complete EHRs, EHR Module(s), and other types of HIT in accordance with the applicable certification criteria adopted by the Secretary in subpart C of this part. It also establishes the processes accreditation organizations must follow to request approval from the National Coordinator and that the National Coordinator in turn will follow to approve an accreditation organization under the permanent certification program as well as certain ongoing responsibilities for an ONC-AA.

#### § 170.502 Definitions.

For the purposes of this subpart:

*Applicant* means a single organization or a consortium of organizations that seeks to become an ONC-ACB by submitting an application for ONC-ACB status to the National Coordinator.

*Deployment site* means the physical location where a Complete EHR, EHR

Module(s) or other type of HIT resides or is being or has been implemented.

*Development site* means the physical location where a Complete EHR, EHR Module(s) or other type of HIT was developed.

*Gap certification* means the certification of a previously certified Complete EHR or EHR Module(s) to:

(1) All applicable new and/or revised certification criteria adopted by the Secretary at subpart C of this part based on the test results of a NVLAP-accredited testing laboratory; and

(2) All other applicable certification criteria adopted by the Secretary at subpart C of this part based on the test results used to previously certify the Complete EHR or EHR Module(s).

*ONC-Approved Accreditor or ONC-AA* means an accreditation organization that the National Coordinator has approved to accredit certification bodies under the permanent certification program.

*ONC-Authorized Certification Body or ONC-ACB* means an organization or a consortium of organizations that has applied to and been authorized by the National Coordinator pursuant to this subpart to perform the certification of Complete EHRs, EHR Module(s), and/or other types of HIT under the permanent certification program.

*Providing or provide an updated certification* means the action taken by an ONC-ACB to ensure that the developer of a previously certified EHR Module(s) shall update the information required by §170.523(k)(1)(i), after the ONC-ACB has verified that the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and that no new certification criteria adopted for privacy and security are applicable to the EHR Module(s).

*Remote certification* means the use of methods, including the use of web-based tools or secured electronic transmissions, that do not require an ONC-ACB to be physically present at the development or deployment site to conduct certification.

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### § 170.503 Requests for ONC-AA status and ONC-AA ongoing responsibilities.

(a) The National Coordinator may approve only one ONC-AA at a time.

(b) *Submission.* The National Coordinator will publish a notice in the FEDERAL REGISTER to announce the 30-day period during which requests for ONC-AA status may be submitted. In order to be considered for ONC-AA status, an accreditation organization must submit a timely request in writing to the National Coordinator along with the following information to demonstrate its ability to serve as an ONC-AA:

(1) A detailed description of the accreditation organization's conformance to ISO/IEC17011:2004 (incorporated by reference in §170.599) and experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (incorporated by reference in §170.599);

(2) A detailed description of the accreditation organization's accreditation, requirements as well as how those requirements would complement the Principles of Proper Conduct for ONC-ACBs and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;

(3) Detailed information on the accreditation organization's procedures that would be used to monitor ONC-ACBs;

(4) Detailed information, including education and experience, about the key personnel who review organizations for accreditation; and

(5) Procedures for responding to, and investigating, complaints against ONC-ACBs.

(c) *Preliminary selection.*

(1) The National Coordinator is permitted up to 60 days from the end of the submission period to review all timely submissions that were received and determine which accreditation organization is best qualified to serve as the ONC-AA.

(2) The National Coordinator's determination will be based on the information provided, the completeness of an accreditation organization's description of the elements listed in paragraph (b) of this section, and each accreditation organization's overall accreditation experience.

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(3) The accreditation organization that is determined to be the best qualified will be notified that it has been selected as the ONC-AA on a preliminary basis, subject to the resolution of the reconsideration process in §170.504. All other accreditation organizations will be notified that their requests for ONC-AA status have been denied. The accreditation organization that is selected on a preliminary basis shall not represent itself as the ONC-AA or perform accreditation(s) under the permanent certification program unless and until it receives written notice from the National Coordinator that it has been approved as the ONC-AA on a final basis pursuant to paragraph (d) of this section.

(4) Any accreditation organization that submits a timely request for ONC-AA status and is denied may request reconsideration in accordance with §170.504.

(d) *Final approval.*

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in §170.504(b), then that organization will be approved as the ONC-AA on a final basis. The accreditation organization that was selected as the ONC-AA on a preliminary basis pursuant to paragraph (c) of this section will be notified of this final decision and cannot request reconsideration or further review.

(2) If the National Coordinator determines that no accreditation organization has met the standard specified in §170.504(b), then the organization that was selected as the ONC-AA on a preliminary basis pursuant to paragraph (c) of this section will be approved as the ONC-AA on a final basis.

(e) *ONC-AA ongoing responsibilities.* An ONC-AA must:

(1) Maintain conformance with ISO/IEC 17011:2004 (incorporated by reference in §170.599);

(2) In accrediting certification bodies, verify conformance to, at a minimum, ISO/IEC Guide 65:1996 (incorporated by reference in §170.599) and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;

(3) Verify that ONC-ACBs are performing surveillance in accordance with their respective annual plans; and

(4) Review ONC-ACB surveillance results to determine if the results indicate any substantive non-conformance by ONC-ACBs with the conditions of their respective accreditations.

(f) *ONC-AA status.*

(1) An accreditation organization has not been granted ONC-AA status unless and until it is notified by the National Coordinator that it has been approved as the ONC-AA on a final basis pursuant to paragraph (d) of this section.

(2) An ONC-AA's status will expire not later than 3 years from the date its status was granted by the National Coordinator.

(3) The National Coordinator will accept requests for ONC-AA status, in accordance with paragraph (b) of this section, at least 180 days before the current ONC-AA's status is set to expire.

**§ 170.504 Reconsideration process for requests for ONC-AA status.**

(a) An accreditation organization that submits a timely request for ONC-AA status in accordance with §170.503 and is denied may request reconsideration of the decision to deny its request for ONC-AA status.

(b) *Submission requirement.* To request reconsideration, an accreditation organization is required to submit to the National Coordinator, within 15 days of receipt of a denial notice, a written statement with supporting documentation contesting the decision to deny its request for ONC-AA status. The submission must demonstrate that clear, factual errors were made in the review of its request for ONC-AA status and that the accreditation organization would have been selected as the ONC-AA pursuant to §170.503(c) if those errors had been corrected. If the National Coordinator does not receive an accreditation organization's submission within the specified timeframe, then its request for reconsideration may be denied.

(c) *Review of submissions.* The National Coordinator is permitted up to 30 days to review all timely submissions that were received and determine whether an accreditation organization

has met the standard specified in paragraph (b) of this section.

(d) *Decision.*

(1) If the National Coordinator determines that an accreditation organization has met the standard specified in paragraph (b) of this section, then that organization will be approved as the ONC-AA on a final basis. All other accreditation organizations will be notified that their requests for reconsideration have been denied.

(2) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

**§ 170.505 Correspondence.**

(a) Correspondence and communication with the National Coordinator shall be conducted by e-mail, unless otherwise necessary. The official date of receipt of any e-mail between the National Coordinator and an accreditation organization requesting ONC-AA status, the ONC-AA, an applicant for ONC-ACB status, or an ONC-ACB is the date on which the e-mail was sent.

(b) In circumstances where it is necessary for an accreditation organization requesting ONC-AA status, the ONC-AA, an applicant for ONC-ACB status, or an ONC-ACB to correspond or communicate with the National Coordinator by regular or express mail, the official date of receipt will be the date of the delivery confirmation.

**§ 170.510 Types of certification.**

Applicants may seek authorization from the National Coordinator to perform the following types of certification:

(a) Complete EHR certification; and/or

(b) EHR Module certification; and/or

(c) Certification of other types of HIT for which the Secretary has adopted certification criteria under subpart C of this part.

**§ 170.520 Application.**

Applicants must include the following information in an application for ONC-ACB status and submit it to the National Coordinator for the application to be considered complete.

(a) The type of authorization sought pursuant to §170.510. For authorization

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to perform EHR Module certification, applicants must indicate the specific type(s) of EHR Module(s) they seek authorization to certify. If qualified, applicants will only be granted authorization to certify the type(s) of EHR Module(s) for which they seek authorization.

(b) General identifying information including:

(1) Name, address, city, state, zip code, and Web site of applicant; and

(2) Designation of an authorized representative, including name, title, phone number, and e-mail address of the person who will serve as the applicant's point of contact.

(c) Documentation that confirms that the applicant has been accredited by the ONC-AA.

(d) An agreement, properly executed by the applicant's authorized representative, that it will adhere to the Principles of Proper Conduct for ONC-ACBs.

### § 170.523 Principles of proper conduct for ONC-ACBs.

An ONC-ACB shall:

(a) Maintain its accreditation;

(b) Attend all mandatory ONC training and program update sessions;

(c) Maintain a training program that includes documented procedures and training requirements to ensure its personnel are competent to certify HIT;

(d) Report to ONC within 15 days any changes that materially affect its:

(1) Legal, commercial, organizational, or ownership status;

(2) Organization and management including key certification personnel;

(3) Policies or procedures;

(4) Location;

(5) Personnel, facilities, working environment or other resources;

(6) ONC authorized representative (point of contact); or

(7) Other such matters that may otherwise materially affect its ability to certify HIT.

(e) Allow ONC, or its authorized agent(s), to periodically observe on site (unannounced or scheduled), during normal business hours, any certifications performed to demonstrate compliance with the requirements of the permanent certification program;

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(f) Provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified, which includes, at a minimum:

(1) The Complete EHR or EHR Module developer name (if applicable);

(2) The date certified;

(3) The product version;

(4) The unique certification number or other specific product identification;

(5) The clinical quality measures to which a Complete EHR or EHR Module has been certified;

(6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary; and

(7) Where applicable, the certification criterion or criteria to which each EHR Module has been certified.

(g) Retain all records related to the certification of Complete EHRs and/or EHR Module(s) for a minimum of 5 years;

(h) Only certify HIT, including Complete EHRs and/or EHR Module(s), that has been tested, using test tools and test procedures approved by the National Coordinator, by a/an:

(1) NVLAP-accredited testing laboratory; or

(2) ONC-ATCB when:

(i) Certifying previously certified EHR Module(s) if the certification criterion or criteria to which the EHR Module(s) was previously certified have not been revised and no new certification criteria are applicable to the EHR Module(s); or

(ii) Performing gap certification.

(i) Submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results; and

(j) Promptly refund any and all fees received for:

(1) Requests for certification that are withdrawn while its operations are suspended by the National Coordinator;

(2) Certifications that will not be completed as a result of its conduct; and

(3) Previous certifications that it performed if its conduct necessitates the recertification of Complete EHRs and/or EHR Module(s);

(k) Ensure adherence to the following requirements when issuing a certification to a Complete EHR and/or EHR Module(s):

(1) A Complete EHR or EHR Module developer must conspicuously include the following on its Web site and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:

(i) "This [Complete EHR or EHR Module] is 20[XX]/20[XX] compliant and has been certified by an ONC-ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments."; and

(ii) The information an ONC-ACB is required to report to the National Coordinator under paragraph (f) of this section for the specific Complete EHR or EHR Module at issue;

(2) A certification issued to a pre-coordinated, integrated bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section, except that the certification must also indicate each EHR Module that is included in the bundle; and

(3) A certification issued to a Complete EHR or EHR Module based solely on the applicable certification criteria adopted by the Secretary at subpart C of this part must be separate and distinct from any other certification(s) based on other criteria or requirements.

**§ 170.525 Application submission.**

(a) An applicant for ONC-ACB status must submit its application either electronically via e-mail (or web submission if available), or by regular or express mail.

(b) An application for ONC-ACB status may be submitted to the National Coordinator at any time.

**§ 170.530 Review of application.**

(a) *Method of review and review time-frame.*

(1) Applications will be reviewed in the order they are received.

(2) The National Coordinator is permitted up to 30 days from receipt to review an application that is submitted for the first time.

(b) *Application deficiencies.*

(1) If the National Coordinator identifies an area in an application that requires the applicant to clarify a statement or correct an error or omission, the National Coordinator may contact the applicant to make such clarification or correction without issuing a deficiency notice. If the National Coordinator has not received the requested information after five days, the National Coordinator may issue a deficiency notice to the applicant.

(2) If the National Coordinator determines that deficiencies in the application exist, the National Coordinator will issue a deficiency notice to the applicant and return the application. The deficiency notice will identify the areas of the application that require additional information or correction.

(c) *Revised application.*

(1) An applicant is permitted to submit a revised application in response to a deficiency notice. An applicant may request from the National Coordinator an extension for good cause of the 15-day period provided in paragraph (c)(2) of this section to submit a revised application.

(2) In order for an applicant to continue to be considered for ONC-ACB status, the applicant's revised application must address the specified deficiencies and be received by the National Coordinator within 15 days of the applicant's receipt of the deficiency notice, unless the National Coordinator grants an applicant's request for an extension of the 15-day period based on a finding of good cause. If a good cause extension is granted, then the revised application must be received by the end of the extension period.

(3) The National Coordinator is permitted up to 15 days to review a revised application once it has been received and may request clarification of statements and the correction of errors or omissions in a revised application during this time period.

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(4) If the National Coordinator determines that a revised application still contains deficiencies, the applicant will be issued a denial notice indicating that the applicant cannot re-apply for ONC-ACB status for a period of six months from the date of the denial notice. An applicant may request reconsideration of this decision in accordance with § 170.535.

*(d) Satisfactory application.*

(1) An application will be deemed satisfactory if it meets all the application requirements, as determined by the National Coordinator.

(2) The National Coordinator will notify the applicant's authorized representative of its satisfactory application and its successful achievement of ONC-ACB status.

(3) Once notified by the National Coordinator of its successful achievement of ONC-ACB status, the applicant may represent itself as an ONC-ACB and begin certifying health information technology consistent with its authorization.

## § 170.535 ONC-ACB application reconsideration.

(a) An applicant may request that the National Coordinator reconsider a denial notice only if the applicant can demonstrate that clear, factual errors were made in the review of its application and that the errors' correction could lead to the applicant obtaining ONC-ACB status.

(b) *Submission requirement.* An applicant is required to submit, within 15 days of receipt of a denial notice, a written statement to the National Coordinator contesting the decision to deny its application and explaining with sufficient documentation what factual error(s) it believes can account for the denial. If the National Coordinator does not receive the applicant's reconsideration request within the specified timeframe, its reconsideration request may be rejected.

(c) *Reconsideration request review.* If the National Coordinator receives a timely reconsideration request, the National Coordinator is permitted up to 15 days from the date of receipt to review the information submitted by the applicant and issue a decision.

*(d) Decision.*

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(1) If the National Coordinator determines that clear, factual errors were made during the review of the application and that correction of the errors would remove all identified deficiencies, the applicant's authorized representative will be notified of the National Coordinator's determination and the applicant's successful achievement of ONC-ACB status.

(2) If, after reviewing an applicant's reconsideration request, the National Coordinator determines that the applicant did not identify factual errors or that the correction of the factual errors would not remove all identified deficiencies in the application, the National Coordinator may reject the applicant's reconsideration request.

(3) *Final decision.* A reconsideration decision issued by the National Coordinator is final and not subject to further review.

## § 170.540 ONC-ACB status.

(a) *Acknowledgement and publication.* The National Coordinator will acknowledge and make publicly available the names of ONC-ACBs, including the date each was authorized and the type(s) of certification each has been authorized to perform.

(b) *Representation.* Each ONC-ACB must prominently and unambiguously identify the scope of its authorization on its Web site and in all marketing and communications statements (written and oral) pertaining to its activities under the permanent certification program.

(c) *Renewal.* An ONC-ACB is required to renew its status every three years. An ONC-ACB is required to submit a renewal request, containing any updates to the information requested in § 170.520, to the National Coordinator 60 days prior to the expiration of its status.

(d) *Expiration.* An ONC-ACB's status will expire three years from the date it was granted by the National Coordinator unless it is renewed in accordance with paragraph (c) of this section.

## § 170.545 Complete EHR certification.

(a) When certifying Complete EHRs, an ONC-ACB must certify in accordance with all applicable certification

criteria adopted by the Secretary at subpart C of this part.

(b) An ONC-ACB must provide the option for a Complete EHR to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC-ACB may provide the option for and perform gap certification of previously certified Complete EHRs.

(d) *Inherited certified status.* An ONC-ACB must accept requests for a newer version of a previously certified Complete EHR to inherit the certified status of the previously certified Complete EHR without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified Complete EHR, an ONC-ACB must review an attestation submitted by the developer of the Complete EHR to determine whether any change in the newer version has adversely affected the Complete EHR's capabilities for which certification criteria have been adopted.

(2) An ONC-ACB may grant certified status to a newer version of a previously certified Complete EHR if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

(e) An ONC-ACB that has been authorized to certify Complete EHRs is also authorized to certify all EHR Modules under the permanent certification program.

#### § 170.550 EHR Module certification.

(a) When certifying EHR Module(s), an ONC-ACB must certify in accordance with the applicable certification criteria adopted by the Secretary at subpart C of this part.

(b) An ONC-ACB must provide the option for an EHR Module(s) to be certified solely to the applicable certification criteria adopted by the Secretary at subpart C of this part.

(c) *Gap certification.* An ONC-ACB may provide the option for and perform gap certification of previously certified EHR Module(s).

(d) An ONC-ACB may provide an updated certification to a previously certified EHR Module(s).

(e) *Privacy and security certification.* EHR Module(s) shall be certified to all privacy and security certification criteria adopted by the Secretary, unless the EHR Module(s) is presented for certification in one of the following manners:

(1) The EHR Modules are presented for certification as a pre-coordinated, integrated bundle of EHR Modules, which would otherwise meet the definition of and constitute a Complete EHR, and one or more of the constituent EHR Modules is demonstrably responsible for providing all of the privacy and security capabilities for the entire bundle of EHR Modules; or

(2) An EHR Module is presented for certification, and the presenter can demonstrate and provide documentation to the ONC-ACB that a privacy and security certification criterion is inapplicable or that it would be technically infeasible for the EHR Module to be certified in accordance with such certification criterion.

(f) *Inherited certified status.* An ONC-ACB must accept requests for a newer version of a previously certified EHR Module(s) to inherit the certified status of the previously certified EHR Module(s) without requiring the newer version to be recertified.

(1) Before granting certified status to a newer version of a previously certified EHR Module(s), an ONC-ACB must review an attestation submitted by the developer(s) of the EHR Module(s) to determine whether any change in the newer version has adversely affected the EHR Module(s)' capabilities for which certification criteria have been adopted.

(2) An ONC-ACB may grant certified status to a newer version of a previously certified EHR Module(s) if it determines that the capabilities for which certification criteria have been adopted have not been adversely affected.

#### § 170.553 Certification of health information technology other than Complete EHRs and EHR Modules.

An ONC-ACB authorized to certify health information technology other than Complete EHRs and/or EHR Modules must certify such health information technology in accordance with the

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applicable certification criterion or certification criteria adopted by the Secretary at subpart C of this part.

### § 170.555 Certification to newer versions of certain standards.

(a) ONC-ACBs may certify Complete EHRs and/or EHR Module(s) to a newer version of certain identified minimum standards specified at subpart B of this part if the Secretary has accepted a newer version of an adopted minimum standard.

(b) *Applicability of an accepted newer version of an adopted minimum standard.*

(1) ONC-ACBs are not required to certify Complete EHRs and/or EHR Module(s) according to newer versions of an adopted minimum standard accepted by the Secretary until the incorporation by reference provision of the adopted version is updated in the FEDERAL REGISTER with a newer version.

(2) Certified EHR Technology may be upgraded to comply with newer versions of an adopted minimum standard accepted by the Secretary without adversely affecting the certification status of the Certified EHR Technology.

### § 170.557 Authorized certification methods.

An ONC-ACB must provide remote certification for both development and deployment sites.

### § 170.560 Good standing as an ONC-ACB.

An ONC-ACB must maintain good standing by:

(a) Adhering to the Principles of Proper Conduct for ONC-ACBs;

(b) Refraining from engaging in other types of inappropriate behavior, including an ONC-ACB misrepresenting the scope of its authorization, as well as an ONC-ACB certifying Complete EHRs and/or EHR Module(s) for which it does not have authorization; and

(c) Following all other applicable Federal and State laws.

### § 170.565 Revocation of ONC-ACB status.

(a) *Type-1 violations.* The National Coordinator may revoke an ONC-ACB's status for committing a Type-1 violation. Type-1 violations include viola-

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tions of law or permanent certification program policies that threaten or significantly undermine the integrity of the permanent certification program. These violations include, but are not limited to: False, fraudulent, or abusive activities that affect the permanent certification program, a program administered by HHS or any program administered by the Federal government.

(b) *Type-2 violations.* The National Coordinator may revoke an ONC-ACB's status for failing to timely or adequately correct a Type-2 violation. Type-2 violations constitute non-compliance with § 170.560.

(1) *Noncompliance notification.* If the National Coordinator obtains reliable evidence that an ONC-ACB may no longer be in compliance with § 170.560, the National Coordinator will issue a noncompliance notification with reasons for the notification to the ONC-ACB requesting that the ONC-ACB respond to the alleged violation and correct the violation, if applicable.

(2) *Opportunity to become compliant.* After receipt of a noncompliance notification, an ONC-ACB is permitted up to 30 days to submit a written response and accompanying documentation that demonstrates that no violation occurred or that the alleged violation has been corrected.

(i) If the ONC-ACB submits a response, the National Coordinator is permitted up to 30 days from the time the response is received to evaluate the response and reach a decision. The National Coordinator may, if necessary, request additional information from the ONC-ACB during this time period.

(ii) If the National Coordinator determines that no violation occurred or that the violation has been sufficiently corrected, the National Coordinator will issue a memo to the ONC-ACB confirming this determination.

(iii) If the National Coordinator determines that the ONC-ACB failed to demonstrate that no violation occurred or to correct the area(s) of non-compliance identified under paragraph (b)(1) of this section within 30 days of receipt of the noncompliance notification, then the National Coordinator may propose to revoke the ONC-ACB's status.

(c) *Proposed revocation.*

(1) The National Coordinator may propose to revoke an ONC-ACB's status if the National Coordinator has reliable evidence that the ONC-ACB has committed a Type-1 violation; or

(2) The National Coordinator may propose to revoke an ONC-ACB's status if, after the ONC-ACB has been notified of a Type-2 violation, the ONC-ACB fails to:

(i) To rebut the finding of a violation with sufficient evidence showing that the violation did not occur or that the violation has been corrected; or

(ii) Submit to the National Coordinator a written response to the non-compliance notification within the specified timeframe under paragraph (b)(2) of this section.

(d) *Suspension of an ONC-ACB's operations.*

(1) The National Coordinator may suspend the operations of an ONC-ACB under the permanent certification program based on reliable evidence indicating that:

(i) The ONC-ACB committed a Type-1 or Type-2 violation; and

(ii) The continued certification of Complete EHRs, EHR Module(s), and/or other types of HIT by the ONC-ACB could have an adverse impact on the health or safety of patients.

(2) If the National Coordinator determines that the conditions of paragraph (d)(1) of this section have been met, an ONC-ACB will be issued a notice of proposed suspension.

(3) Upon receipt of a notice of proposed suspension, an ONC-ACB will be permitted up to 3 days to submit a written response to the National Coordinator explaining why its operations should not be suspended.

(4) The National Coordinator is permitted up to 5 days from receipt of an ONC-ACB's written response to a notice of proposed suspension to review the response and make a determination.

(5) The National Coordinator may make one of the following determinations in response to the ONC-ACB's written response or if the ONC-ACB fails to submit a written response within the timeframe specified in paragraph (d)(3) of this section:

(i) Rescind the proposed suspension; or

(ii) Suspend the ONC-ACB's operations until it has adequately corrected a Type-2 violation; or

(iii) Propose revocation in accordance with §170.565(c) and suspend the ONC-ACB's operations for the duration of the revocation process.

(6) A suspension will become effective upon an ONC-ACB's receipt of a notice of suspension.

(e) *Opportunity to respond to a proposed revocation notice.*

(1) An ONC-ACB may respond to a proposed revocation notice, but must do so within 10 days of receiving the proposed revocation notice and include appropriate documentation explaining in writing why its status should not be revoked.

(2) Upon receipt of an ONC-ACB's response to a proposed revocation notice, the National Coordinator is permitted up to 30 days to review the information submitted by the ONC-ACB and reach a decision.

(f) *Good standing determination.* If the National Coordinator determines that an ONC-ACB's status should not be revoked, the National Coordinator will notify the ONC-ACB's authorized representative in writing of this determination.

(g) *Revocation.*

(1) The National Coordinator may revoke an ONC-ACB's status if:

(i) A determination is made that revocation is appropriate after considering the information provided by the ONC-ACB in response to the proposed revocation notice; or

(ii) The ONC-ACB does not respond to a proposed revocation notice within the specified timeframe in paragraph (e)(1) of this section.

(2) A decision to revoke an ONC-ACB's status is final and not subject to further review unless the National Coordinator chooses to reconsider the revocation.

(h) *Extent and duration of revocation.*

(1) The revocation of an ONC-ACB is effective as soon as the ONC-ACB receives the revocation notice.

(2) A certification body that has had its ONC-ACB status revoked is prohibited from accepting new requests for

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certification and must cease its current certification operations under the permanent certification program.

(3) A certification body that has had its ONC-ACB status revoked for a Type-1 violation, is not permitted to reapply for ONC-ACB status under the permanent certification program for a period of 1 year.

(4) The failure of a certification body that has had its ONC-ACB status revoked to promptly refund any and all fees for certifications of Complete EHRs and EHR Module(s) not completed will be considered a violation of the Principles of Proper Conduct for ONC-ACBs and will be taken into account by the National Coordinator if the certification body reapplies for ONC-ACB status under the permanent certification program.

### **§ 170.570 Effect of revocation on the certifications issued to Complete EHRs and EHR Module(s).**

(a) The certified status of Complete EHRs and/or EHR Module(s) certified by an ONC-ACB that had its status revoked will remain intact unless a Type-1 violation was committed that calls into question the legitimacy of the certifications issued by the former ONC-ACB.

(b) If the National Coordinator determines that a Type-1 violation occurred that called into question the legitimacy of certifications conducted by the former ONC-ACB, then the National Coordinator would:

(1) Review the facts surrounding the revocation of the ONC-ACB's status; and

(2) Publish a notice on ONC's Web site if the National Coordinator believes that Complete EHRs and/or EHR Module(s) were improperly certified by the former ONC-ACB.

(c) If the National Coordinator determines that Complete EHRs and/or EHR Module(s) were improperly certified, the certification status of affected Complete EHRs and/or EHR Module(s) would only remain intact for 120 days after the National Coordinator publishes the notice. The certification sta-

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tus of affected Complete EHRs and/or EHR Module(s) can only be maintained thereafter by being re-certified by an ONC-ACB in good standing.

### **§ 170.599 Incorporation by reference.**

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the Department of Health and Human Services must publish notice of change in the FEDERAL REGISTER and the material must be available to the public. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030 or go to [http://www.archives.gov/federal\\_register/code\\_of\\_federal\\_regulations/ibr\\_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Also, it is available for inspection at U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave., SW., Washington, DC 20201, call ahead to arrange for inspection at 202-690-7151, and is available from the source listed below.

(b) International Organization for Standardization, Case postale 56, CH-1211, Geneve 20, Switzerland, telephone +41-22-749-01-11, <http://www.iso.org>.

(1) ISO/IEC 17011:2004 Conformity Assessment—General Requirements for Accreditation Bodies Accrediting Conformity Assessment Bodies (Corrected Version), February 15, 2005, IBR approved for § 170.503.

(2) ISO/IEC GUIDE 65:1996—General Requirements for Bodies Operating Product Certification Systems (First Edition), 1996, IBR approved for § 170.503.

(3) [Reserved]

## **PARTS 171-199 [RESERVED]**